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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,789	09/12/2001	Charlie Ricci	018413-378	8809
7590	10/21/2003		EXAMINER	
Robert E. Krebs BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			SHARAREH, SHAHNAM J	
		ART UNIT	PAPER NUMBER	1617
		DATE MAILED: 10/21/2003		18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/954,789	RICCI ET AL.
Examiner	Art Unit	
Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 16, 20-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 16, 20-29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 23, 2003 has been entered.

Claims 16, 20-29 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16, 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrory US Patent 5,951,599 in view of Chuter et al (J Vasc Surg 2000,; 31:122-33), May J Vasc Surg 2000; 32:124-129) and Evans et al US Patent 5,695,480.

McCrory teaches occlusive systems including a stent for deployment in the parent vessel and a polymeric embolizing composition to seal aneurysm sac (see abstract, col 5, lines 25-58; col 6, lines 15-60; col 12, lines 13-25). McCrory does not teach stent grafts.

Chuter and May collectively teach that stent grafts and stents are interchangeably used in the art to treat vascular aneurysm. Specifically, Chuter describes endovascular repair methodologies in patients using stent grafts (abstract; pages 126-130). May describes that both first generation prostheses, such as stents, and second generation prostheses, such as stent grafts, are effective in treating abdominal aortic aneurysm (see abstract, table III at page 127; pages 127-129).

Evans is merely used to show that assembling a kit for vascular repair procedure comprising an embolic polymeric composition that can solidify in vivo, and a prosthetic device such as a metal coil with different size catheters for delivering the composition

and arresting the blood flow during the procedure (see abstract, col 4, lines 26-47; col 10, lines 31-41; col 11, lines 52-67; col 13, lines 1-43). Evens fails to teach the stent graft in his kits.

However, it is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, claims that require no more than mixing together of conventional elements used in the art for the same purpose set forth *prima facie* obvious subject matter. *In re Kerkhoven*, 205 USPQ 1069(CCPA) 1980. In the instant case, all elements of the instant claims are taught in the art. Accordingly, it would have been obvious at the time of invention to add a stent grafts taught by Chutter and May to McCrory's system and assemble a kit to facilitate convenience during a vascular repair procedure as taught by Evens.

Moreover, as shown by Chutter and May Stent grafts and Stents are art recognized equivalent in the art of treating vascular repair. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute the Stent of McCrory's system with a Stent graft taught in May and form a surgical kit as shown by Evans, because the ordinary skill in the art would have had a reasonable expectation of success in achieving similar therapeutic results as McCrory.

Response to Arguments

Applicant's arguments filed July 23, 2003 have been fully considered but they are not persuasive.

Applicant argues that McCrory's device is used for aneurysm with bubble like sacs and that modification of McCrory's device would destroy the ability of McCrory's device to allow blood flow into perforating vessels. Accordingly, Applicant appears to be arguing that the cited references are not combinable.

In response, the scope of the pending claims is directed to kits comprising a stentgraft, a catheter and a polymeric composition. McCrory uses a stent instead of a stentgraft. However, the secondary references elaborate that in the art of assembling kits for surgical convenience, stents and stentgrafts are viewed to be art equivalents. Therefore, substituting stent graft in lace of a stent in the kit of McCrory would have been obvious. In addition, contrary to Applicant's arguments, the rejection of record does not require modification of the stent, rather the components of the kit that contains it. Accordingly, the rejection is proper.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.



Shahnam Sharareh, PharmD
Patent Examiner, AU 1617

ss

10/14/03